

FORM PTQ-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE
(REV. 9-2006)TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER

001107.00617

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/591,347

INTERNATIONAL APPLICATION NO.
PCT/US2005/005193INTERNATIONAL FILING DATE
18 February 2005PRIORITY DATE CLAIMED
02 March 2004

TITLE OF INVENTION

Mutations of the PIK3CA Gene in Human Cancers

APPLICANT(S) FOR DO/EO/US

SAMUELS, Yardená *et al.*

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (25) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 23 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ An Application Data Sheet under 37 CFR 1.76.
18. ☐ A substitute specification.
19. ☐ A power of attorney and/or change of address letter.
20. ☒ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
21. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
22. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
23. ☐ Express Mail Label No.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| | | |
|---|---|--|
| U.S. APPLICATION NO (if known, see 37 CFR 1.5) 10/591,347 | INTERNATIONAL APPLICATION NO. PCT/US2005/005193 | ATTORNEY'S DOCKET NUMBER 001107.00617 |
| 24. Other items or information: Response to Notification of Missing Requirements, Copy of the Notification of Missing Requirements, Petition for Extension of Time Under 37 CFR 1.136(a), CRF and paper form Sequence Listing cover letter. | | |
| The following fees have been submitted: 25. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)). \$300 | | CALCULATIONS PTO USE \$ \$0.00 |
| 26. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article as an International Searching Authority. \$0 All other situations. \$200 | | \$ \$0.00 |
| 27. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4). . . \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority. \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB. \$400 All other situations. \$500 | | \$ \$0.00 |
| TOTAL OF 25, 26 and 27 = | | \$ \$0.00 |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole) |
| - 100 = | 0 /50 = | 0 |
| | | x \$250.00 |
| | | \$ \$0.00 |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). | | \$ \$130.00 |
| CLAIMS | NUMBER FILED | NUMBER EXTRA |
| Total claims | - 20 = | 0 |
| Independent claims | - 3 = | 0 |
| | | x \$200.00 |
| | | \$ \$0.00 |
| MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00 | | \$ \$0.00 |
| TOTAL OF ABOVE CALCULATIONS = | | \$ \$130.00 |
| <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | \$ \$65.00 |
| SUBTOTAL = | | \$ \$65.00 |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | \$ \$0.00 |
| TOTAL NATIONAL FEE = | | \$ \$65.00 |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property + | | \$ \$40.00 |
| TOTAL FEES ENCLOSED = | | \$ \$105.00 |
| 06/18/2007 GFREY1 00000036 190733 10591347 | | Amount to be \$ |
| 01 FC:26:7 65.00 DA | | Amount to be \$ |

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 19-0733 in the amount of \$ \$105.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0733. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038. The PTO-2038 should only be mailed or faxed to the USPTO. However, when paying the basic national fee, the PTO-2038 may NOT be faxed to the USPTO.

ADVISORY: If filing by EFS-Web, do **NOT** attach the PTO-2038 form as a PDF along with your EFS-Web submission.
Please

be advised that this is not recommended and by doing so your credit card information may be displayed via PAIR. To

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Banner & Witcoff, Ltd.
Customer Number 22907


SIGNATURE

Sarah A. Kagan

NAME

32,141

REGISTRATION NUMBER

14 June 2007

DATE

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|--|---|-------------------------------|
| In re application of: |) | |
| |) | |
| Yardena SAMUELS <i>et al.</i> |) | Group Art No. TBA |
| |) | |
| Serial No.: 10/591,347 |) | Examiner: TBA |
| |) | |
| Filed: August 31, 2006 |) | Atty. Docket No: 001107.00617 |
| |) | |
| For: Mutations of the PIK3CA Gene in Human |) | |
| Cancers |) | |

RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER
35 U.S.C. 371 IN THE DO/EO/US

Commissioner of Patents
U.S. Patent and Trademark Office
Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

In response to the Notification Of Missing Requirements Under 35 U.S.C. 371 In The United States Designated/Elected Office (DO/EO/US) dated March 14, 2007, Applicants submit herewith the following documents to complete the requirements for acceptance under 35 USC 371:

1. Fee Transmittal Sheet Form PTO-1390 (Modified) in Duplicate;
2. Copy of the Notification of Missing Requirements;
3. Executed Declaration for Patent Application;
4. Submission of CRF and paper form of Substitute Sequence Listing;
5. Petition for extension of time & payment of fees;
6. Request for Recordation of Assignment.

The Commissioner for Patents is authorized to charge our Deposit Account No. 19-0733 in the amount of \$165.00, as follows:

\$ 65.00 Late declaration surcharge (small entity)

\$ 60.00 Petition for extension of time & payment of fees (small entity)

\$ 40.00 Recordation of assignment fee

It is not believed that any additional fees are required. However, in the event that additional fees are necessary, then such fees are authorized to be charged to our Deposit Account No. 19-0733.

Respectfully submitted,

BANNER & WITCOFF, LTD.

By: 
Sarah A. Kagan
Registration No. 32,141

Date: June 14, 2007

Banner & Witcoff Ltd
Customer Number: 22907

SAK:sdm



UNITED STATES PATENT AND TRADEMARK OFFICE

RUSH!

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

| | | |
|---|--|----------------------------------|
| U.S. APPLICATION NUMBER NO. 10/591,347 | FIRST NAMED APPLICANT Yardena Samuels | ATTY. DOCKET NO. 001107.00617 |
|---|--|----------------------------------|

22907
 BANNER & WITCOFF, LTD.
 1100 13th STREET, N.W.
 SUITE 1200
 WASHINGTON, DC 20005-4051

001107.00617

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| INTERNATIONAL APPLICATION NO. |
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PCT/US05/05193

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| I.A. FILING DATE 02/18/2005 | PRIORITY DATE 03/02/2004 |
|--------------------------------|-----------------------------|

CONFIRMATION NO. 6442

371 FORMALITIES LETTER



OC000000022853514

Date Mailed: 03/14/2007

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 08/31/2006
- Information Disclosure Statements filed on 08/31/2006
- Biochemical Sequence Diskette filed on 08/31/2006
- Biochemical Sequence Listing filed on 08/31/2006
- Request for Immediate Examination filed on 08/31/2006
- U.S. Basic National Fees filed on 08/31/2006
- Priority Documents filed on 08/31/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$65 for a Small Entity:

153/2/07
 Docketed 3/19/07
 Attny SAK
 Case Ref 001107.00617
 Action Missing Reqs. Due
 Due Date 5/14/07
 Last Day 10/14/07
 By cd

- **\$65 Surcharge.**

- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1:5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

INDIA L EVANS

Telephone: (703) 308-9140 EXT 212

PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/591,347 | PCT/US05/05193 | 001107.00617 |